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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,567	07/06/2001	Carlos Plata-Salaman	ORT-1453	4092

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AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
FONDA, KATHLEEN KAHLER	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,567	PLATA-SALAMAN ET AL.	
	Examiner	Art Unit	
	Kathleen Kahler Fonda, Ph.D.	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8-29-01 (IDS)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) # 5
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The Examiner notes that no dates have been provided with references BA-BG submitted with the Information Disclosure Statement of 08-29-01. Although each of these references has been considered, Applicant is advised that they cannot be printed on the face of any patent which may issue from this application unless at least the year is provided. With respect to examination of the claims, the documents have been treated as prior art because the Examiner notes that Applicant has identified the documents as "Other Prior Art--Non-Patent Literature Documents."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 is indefinite because although it reads on a method of preventing development of Type II diabetes, it also states that the subject mammal is "afflicted with such condition."

Claims 5 and 15 are similarly indefinite with regard to "Syndrome X" and "skin lesions associated with Type II diabetes mellitus or Syndrome X" respectively. There would appear to be a mismatch between prevention and pre-existing affliction. Thus the metes and bounds of the claim cannot be determined.

Claims 1, 6, 10, 15, and 20 are indefinite because they fail to recite any steps of the method. None of these independent claims requires administration of the compound of formula I to any subject.

Claim 5 is indefinite because it is not clear whether the parenthetical expression in "Syndrome X (Insulin Resistance Syndrome, Metabolic Syndrome, or Metabolic Syndrome X)" is intended to limit the claim. Thus the metes and bounds cannot be determined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use

or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 10, 11, 15, 16, 20, and 21 are rejected under 35 U.S.C. 102(a) and/or (b) as being anticipated by EDWARDS *et al*. (U). EDWARDS teaches administration of topiramate for treatment of diabetic neuropathy in patients suffering from diabetes. Because EDWARDS does not specifically state whether the patients had Type I (juvenile) or Type II (adult-onset) diabetes, but does state that 26 patients ages 36 to 77 years were treated, it is reasonable to conclude that at least some of the 26 patients had Type II diabetes. As for claim 10, the patients of EDWARDS are mammals suffering from impaired oral glucose tolerance, so the limitations of the claim are met. Although EDWARDS does not state that the patients have existing skin lesions, the preventive aspect of claim 15 is met by the EDWARDS reference. As for claim 20, the patients of EDWARDS are mammals suffering from defective insulin sensitivity, so the

limitations of the claim are met. Thus the claims are anticipated.

Claims 1-24 are rejected under 35 U.S.C. 102(a) and/or (b) as being anticipated by OSBORNE *et al.* (BA). OSBORNE teaches administration of topiramate at a dosage of 10, 30, 100, and 300 mg/kg/day to mice which are animal models of Type II diabetes mellitus; see the abstract. Thus claims 1-4, 10-14, and 20-24 are anticipated as to treatment, and claims 5-9 and 15-19 are anticipated as to prevention.

Claims 1-24 are rejected under 35 U.S.C. 102(a) and/or (b) as being anticipated by DEMAREST *et al.* (BC). DEMAREST teaches administration of topiramate at a dosage of 30 and 100 mg/kg/day to mice which are animal models of Type II diabetes mellitus; see the abstract. Thus claims 1-4, 10-14, and 20-24 are anticipated as to treatment, and claims 5-9 and 15-19 are anticipated as to prevention.

Claims 1-9 and 15-19 are rejected under 35 U.S.C. 102(a) and/or (b) as being anticipated by CROOKE *et al.* (BE). CROOKE teaches administration of topiramate at a dosage of 20, 60, and

180 mg/kg/day to obese mice; see the abstract. Thus the claims are anticipated as to prevention.

Claims 1-24 are rejected under 35 U.S.C. 102(a) and/or (b) as being anticipated by DEMAREST *et al.* (BF). DEMAREST teaches administration of topiramate at a dosage of 30 and 100 mg/kg/day to mice which are animal models of Type II diabetes mellitus; see the abstract. Thus claims 1-4, 10-14, and 20-24 are anticipated as to treatment, and claims 5-9 and 15-19 are anticipated as to prevention.

Claims 1-9 and 15-19 are rejected under 35 U.S.C. 102(a) and/or (b) as being anticipated by OSBORNE *et al.* (BG). OSBORNE teaches administration of topiramate at a dosage of 10, 30, 110, and 300 mg/kg/day to obese mice; see the abstract. Thus the claims are anticipated as to prevention.

Claims 1-9 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by SHANK (CA). SHANK teaches administration of compounds within the scope of the pending claims, including topiramate, at a dosage of about 50 to 400 mg or about 25 to 200 mg, to mammals suffering from obesity; see the claims of SHANK. Thus the pending claims are anticipated as to prevention.

No claim is allowed.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30 a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be

directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
Art Unit 1623